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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,856	01/03/2006	Karine Deffez	ON/4-32680A	9612

1095 7590 05/26/2010

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
05/26/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,856	DEFFEZ ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-7,9-15 and 22-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-7,9-15 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/4/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 3/4/10 was filed after the mailing date of the First Action on the Merits on 9/18/09. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Election/Restrictions

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4-7, 9-15, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Lattmann et al (WO 97/49395 hereafter '395) in view of Patel et al (USPN 5,698,221 hereafter '221).

The '395 patent teaches a dispersible tablet formulation comprising deferasirox/deferacirox, the compound (I) of the instant claims (abstract). The compound is present in the formulation in a concentration from 0.1-50% (pg. 10, ¶ 1). The tablets comprise excipients such as fillers like, lactose, sucrose and mannitol, disintegrants such as starches, binders such as polyvinylpyrrolidone, lubricants such as magnesium stearate, glidants, and

surfactants (pg. 9, ¶ 3- pg. 8, ¶ 2). The dosage form is administered to a patient in need there of in a concentration from 20-80 mg/kg (pg. 9 ¶ 3). The compounds are present in free acid and crystal forms (pg. 15, ¶ 6-pg. 16, ¶ 3). The '395 patent discloses a dispersible tablet comprising deferasirox and a series of excipients including fillers, binders, disintegrants, glidants, surfactants and lubricants. The compound is an iron chelator and can be used to treat iron overload (abstract, page 1, ¶ 1-3). The reference is silent to the specific concentrations of these compounds, however their presence and concentrations are well known in the art as seen in the '221 patent.

The '221 patent discloses a dispersible tablet comprising compounds useful for the treatment of Alzheimer's disorders (abstract). The tablets of the reference disperse in less than 2 minutes (col. 2, lin. 38-42). The active compound is present in a concentration from 15-50% of the tablet, and in an amount from 50-800 mg (col. 5, lin. 21-41). The tablet formulation comprises fillers in concentration from 30-50% (col. 7, lin. 25-28), disintegrants up to 30% (col. 5, lin. 55-60), binders from 1-5% (col. 6, lin. 39-42), at least one surfactant from 0.05-1% (col. 7, lin. 45-50), glidants from 0.2-0.5% (col. 7, lin. 55-58) and a lubricant such as magnesium stearate in a concentration from 0.25-1% (col. 7, lin. 29-30). The tablets are formed by mixing the components together, wet granulating them together, along with lubricants, and compressing the dried mixture into tablets (col. 8, lin. 19-col. 9, lin. 15). It would have been obvious to combine the specific formulation of the '221 patent with the formulation of the '395 since both patents disclose dispersible tablets comprising Alzheimer's medications.

Regarding the specific concentrations and ranges of the instant claims it is the position of the Examiner that these limitations are obviated by the prior art combination. The general

conditions of the claims have been met, namely a fast dispersing tablet formulation comprising deferasirox/deferacirox, fillers, disintegrants, binders, surfactants, glidants and lubricants, identical to those of the instant claims. Each component is present in a range either within or close to the concentrations of the instant claims. These result effective parameters affect the stability, processing speed, strength and dispersible time of the fast dissolving tablets. Each of them can be manipulated and optimized in order to arrive at an optimal dispersible tablet. The fillers can be decrease, and disintegrants increased to decrease dissolution time. The binder can be increased and the tablet strength can be increased. These components each have an affect on the overall composition and can each be optimized through routine experimentation. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955). Each of the components represents a parameter of the dispersible table effects the dissolution time

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With these things in mind it would have been obvious to combine the prior art in order to provide an improved dispersible tablet. The '395 patent is suggestive of the inclusion of specific compounds and the '221 patent provides the specific compounds in the appropriate concentration

in order to provide an improved formulation and process of making said formulation. The formulation would dissolve quickly providing an immediate dose to the patient in need of relief. The fillers, binders and disintegrants would provide protection from environmental damage, while the lubricants would ease the production of the tablets. One of ordinary skill in the art would have been motivated to combine the art as such with an expected result of a stable Alzheimer's drug treatment.

Response to Arguments

Applicant's arguments filed 3/4/10 have been fully considered but they are not persuasive. Applicant argues that:

The combination of the '395 and '221 patent does not obviate the instant claims since the active agents are different and the '395 patent does not teach or suggest how to make dispersible tablets.

Regarding this argument it remains the position of the Examiner that the combination continues to obviate the instant claims. The '395 patent discloses a pharmaceutical formulation comprising desferrioxamine (compound I), disintegrants and other excipients. The formulation can take the form of dispersible tablets. The compound is effective in treating Alzheimer's disease along with iron overload. The reference is however silent to the specific concentrations of the disintegrants of the instant claims. However the optimization of the disintegrating agents would have been obvious to one of ordinary skill in the art, since disintegrants are well known in the art of tabletting and their concentration is known to determine dissolution time and drug release. This can be seen in the '221 patent, where dispersible tablets are formed using

Alzheimer's drugs, and disintegrants. Since both patents disclose drugs that can be used for the same purpose within the same field of endeavor it would have been obvious to optimize the excipient concentrations of the '325 patent as seen in the '221 patent. Despite the difference of the active agents, their compounds remain within the same field of endeavor ad can be used to solve the same problem, namely treating Alzheimer's Disease using dispersible tablets comprising the drug and disintegrants. The '325 patent suggestive of making dispersible tablets (page 8, ¶ 2), while the '221 patent clearly discloses method of making water dispersible tablets that fully disperse within 5 minutes (abstract, col.'2, lin. 60-64). It would have been obvious to follow the suggestion of the '325 patent and look to the teachings of the '221 patent in order to forma dispersible tablet that would be useful for treating Alzheimer's disease and iron overload. This tablet would be able to disperse fully under 5 minutes. For these reasons the claims remain obviated.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618